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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,909	11/16/2001	Joan M. Fallon	8016-5	3427

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EXAMINER	
LUCAS, ZACHARIAH	

ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
04/12/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	09/990,909	FALLON, JOAN M.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,7 and 30-64* is/are pending in the application.

4a) Of the above claim(s) *30-35,39-44 and 50-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,7,36-38,45-49 and 56-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/3/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 2, 7, and 30-64 are pending in the present application.

2. In the prior action, mailed on July 27, 2004, claims 1, 2, and 7 were under consideration and rejected.

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

In view of the grant of the Petition to Revive and Unintentionally Abandoned Application on January 27, 2010, the Applicant's submission filed on November 13, 2009 has been entered.

4. Claims 30-35, 39-44, and 50-55 are drawn to non-elected species of the claimed invention. See, the Requirement for Information, in the form of replacing Figure 4 of the application with a corrected figure, is noted. The Restriction Requirement of May 2002 and the Response thereto of June 2002.

5. Claims 1, 2, 7, 36-38, 45-49, and 56-64 are under consideration.

Information Disclosure Statement

6. The information disclosure statement (IDS) submitted on March 3, 2010, is substantially in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

7. References 51 and 59 have not been considered as no English language copy or statement regarding the relevance of the references has been provided.

Specification

8. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d) (1) and MPEP § 608.01(o). Correction of the following is required: Claims 56-64 have been added to the specification. There does not appear to be any antecedent basis support in the specification for the limitations of these claims.

With respect to claims 56-61, it is noted that nothing in the application provides any specific indication that such limitations were considered to be part of the inventive method. However, it is noted that the teachings of applications teaching such material was incorporated by reference on page 2 of the application. Applicant is therefore requested to amend the present application to provide antecedent basis support for such limitations.

With respect to claims 62-64, while the application indicates on pages 12-13 that children diagnosed with Autism using conventional tests were tested for the present of the indicated pathogens, the specification does not specifically teach a method incorporating both such

conventional tests and the claimed method of diagnosis based on the presence of one or more pathogen infections.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. **(New Rejection)** Claims 1, 2, 7, 36-38,45-49, and 56-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is treated as representative. This claim includes steps of obtaining a sample from a patient, analyzing the sample to determine the presence or absence of one or more antigens from a provided list of pathogens, and "identifying the presence of the one or more different pathogens in the stool sample as a biomarker that indicates that the individual has autism."

It is not clear what is meant by the quoted language. In particular, on its face, the claims appear to indicate that the claimed method requires that those performing the claimed assay must determine for themselves if the one or more antigens screened for actually represent biomarkers for autism. It appears that the Applicant intended that the presence of the antigens were to be used as biomarkers for Autism. It is therefore suggested that the claims be amended to delete the last clause of the claimed method, and replace it with a statement such as follows" wherein the presence of the one or more antigens associated with the different pathogens in the stool sample are biomarkers indicating that the individual has Autism."

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. **(Prior Rejection- Restated as Necessitated by Amendment and Maintained)** Claims 1, 2, and 7 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while apparently being enabling for diagnosing autism, by detecting the presence of antigens from a plurality of pathogens listed, for example, in Figure 3 or on page 9 of the application, does not reasonably provide enablement for methods of such diagnosis by detecting antigens of plurality of other pathogens. This rejection is extended to newly presented claims 36-38, 45-49, and 56-64 for the reasons of record, and the reasons presented below.

It is noted that the claims have been amended or drafted to limit them to the detection of specific pathogenic antigens, the presence of which would be (according to the claim) indicative of the presence of, or potential for the development of, autism. However, rather than requiring the presence of each of the indicated infections, the claims have been amended to indicate that the mere detection of only one or more of the pathogens (such as *H.* pylori) would be indicative of autism (or the development of the disorder) in the patient. As was indicated in the actions mailed on July 30, 2002 and July 29, 2003, the evidence provided by the Applicant does not demonstrate a clear correlation between the presence of any one of the indicated pathogens and autism. As indicated in the prior actions, the teachings of the present application indicate that

persons with Autism tend to have infectious by multiple pathogens. However, the teachings of the application also indicate that the specific pathogens present in autistic patients vary from person to person. There is no demonstration that the presence of antigens from any one pathogen would tend to indicate the presence of future potential for developing autism. Moreover, with respect to the elected species of *H. pylori*, it is further noted that the art indicates that the presence of this pathogen may be indicative of other disorders than autism. See e.g., action mailed in July 2003, pages 10-11.

In traversal of the rejection, the Applicant refers to certain teachings in the application. However, these asserted teachings do not appear to be supported by the data in either the application or in the art for the reasons indicated above and in the prior actions. The arguments are therefore not found persuasive.

New claims 47-49, 58, 61, and 64 have been added to the application. These claims are drawn to methods for determining if a person is at increased risk of developing autism based on the presence of one of more antigens associated with infection by the indicated pathogens. These claims are rejected on the grounds indicated with respect to claims 1, 2, and 7 on pages 6-7 of the action mailed on July 29, 2003 and pages 4-5 of the action mailed on July 30, 2002.

In addition, claims 62-64 each require that the individual "further exhibits one or more symptoms of autism." However, it is noted that autistic disorders are diagnosed on the basis on the presence of multiple symptoms, wherein the mere presence of a single symptom would not appear to be indicative of the presence or development of the disorder. See e.g., Filipek et al., J

Autism Dev Disord 29:439-84 (esp. pages 443-46), and Happé et al., Brain, 119:1377-400, at 1379 (indicating that autism and other PDDs require the presence of serious impairments in more than one area of development- i.e. requiring the presence of multiple "symptoms" of autism). Thus, in view of the lack of correlation of the presence of any one of the indicated infections with autism, and the fact that no single symptom of autism would be sufficient to diagnose the presence of the disorder, and as there is no indication that the combination of these two diagnostic elements would correlate with a clinical diagnosis of autism, these claims are not considered to overcome the enablement problems of the independent claims.

13. **(Prior Rejection- Restated as Necessitated by Amendment)** Claims 1, 2, and 7 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In view of the amendments to the claims, the rejection is withdrawn from claims 1, 2, and 7.

However, new claims 62-64 have been added to the application.

Claims 62-64 require that the individual further exhibits one or more symptoms of autism (thereby indicating that the claimed methods are relying on the presence of such additional symptoms as additional factors in the diagnosis of Autism). It is noted that there does not appear to be any specific support for such limitations in the application as filed. These claims are therefore rejected as presenting New Matter into the application.

Conclusion

14. No claims are allowed.

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Andrew J. Wakefield, GB 2,347742. This reference teaches a method for diagnosing RBD (also referred to as autism) based on the detection of for MMR antigens. However, these antigens are not among those identified by the present claims.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/
Primary Examiner, Art Unit 1648